



Medline Industries, Inc.

One Medline Place  
Mundelein, Illinois 60060.4486

1.847.949.3109  
1.800.950.0128  
Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs  
**510(K) SUMMARY**

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February 19, 1997

1. **Submitters Information:**  
Medline Industries, Inc.  
Dynacor Division  
One Medline Place  
Mundelein, IL 60060  
Phone: 847-949-5500  
Fax: 847-949-2643  
Contact: Christine Galea  
Corporate Regulatory Affairs  
MAR 11 1997
2. **Device Information:**  
A. Trade Name: Medline Employee Protection Kit  
B. Common Name: Employee Protection Kit
3. **Substantial Equivalence Claim:**  
Medline claims substantial equivalence to K952962, EZ Personal Protection Kit, made by Safetec of America, Inc.
4. **Device Description:** Medline Employee Protection Kits are an assemblage of medical and non-medical materials to be used by employees who may need protection from body fluids or other potentially hazardous situations where employee protection may be needed. The kits will be assembled using Medline and other manufacturer's medical devices and materials.

The devices are custom to our customers who specify the contents, quantity and placement of the individual items kit. Attached is a list of individual components that are likely to be in any of these kits. These items are standard and we expect that only quantities will change from one kit to another. The customer may also specify a specific brand of similar items or minor variations of items.

These kits are non-sterile and are shrink-wrapped to maintain kit integrity and cleanliness.



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5. **Intended Use:**  
Medline Personal Protection Kits are intended for use by, but not limited to, hospitals and medical centers. The original intended use of the medical products assembled in these kits will not be changed.

6. **Technological Characteristics:**  
There are no technological differences between the new device and the predicate device.

From the above data, we have determined that the Medline Medline Employee Protection Kits are substantially equivalent in design and performance to K952962, EZ Personal Protection Kit marketed by Safetec of America, Inc.

The safety and effectiveness of Medline Employee Protection Kit is dependent upon proper usage of the products and medical devices that are present in each type of kit.

## EXHIBIT 1

Medline Component List of items most likely to be used in our Employee Protection Kit.

### COMPONENT LIST

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COMPONENT	REGULATORY STATUS
Glass Free Mask	K875172
Glove, Exam Latex	K962094
Goggles, Vents Standard	Not A Medical Device
Isolation Gown	Pre-Amendment Exempt
Latex Glove Powder Free	K962095
Liner 7 X 17 W/Polymer	Not A Medical Device
Sheer Fit Cap, Blue 24" (bouffant cap)	Pre-Amendment Exempt
Shieldmate Mask W/Ties	Pre-Amendment Exempt
Shoe Cover Impervious, White Bulk	Pre-Amendment Exempt
Shoe Cover Spunbond Non-Conductive	Pre-Amendment Exempt